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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,458	08/30/2001	Dwight D. Weller	50450-8038.US00	9454

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EXAMINER	
KIM, YOUNG J	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,458	WELLER ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,15-17 and 19-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,15-17 and 19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of record has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

Preliminary Remark

All rejections hereto not reiterated are considered to be withdrawn.

Claims 1-11, 15-17, and 19-27 are pending and are under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 15-17, and 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependent claims 2-11, 15-17, and 19-27 are indefinite for the recitation of the phrase, "separating a population of ***duplexes comprising*** different oligomeric analyte molecules, wherein said molecules are composed of linked subunits...and are able to hybridize via Watson-Crick base pairing with a specific probe molecule," because it is unclear what the "duplexes" are made of. When read in light of the specification, it appears that a duplex is formed between an oligomeric analyte molecule and a probe. However, the above phrase only recites that the duplex is made of different oligomeric analyte molecules ***without*** the probe molecules hybridized thereto.

Claim 6 is indefinite for the recitation of the phrase, "the probe has a length equal to or no more than 25% greater than the selected sequence," because two different ranges

are combined ("no more than" combined with "25% greater"), resulting in an indefinite metes and bounds of the probe length. For the purpose of prosecution, the phrase has been assumed to read, "the probe has a length equal to or no more than 25% of the selected sequence."

Claims 16 and its dependent claim 17 recite the limitation "the charge bearing ***support.***" There is insufficient antecedent basis for this limitation in the claim. For the purpose of prosecution, the phrase has been assumed to read, "the charge bearing separation medium," finding its proper support from their parent claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 16, 17, 19, 20, and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummins et al. (U.S. Patent No. 5,874,213, issued February 23, 1999).

Cummins et al. disclose a method of employing an oligonucleotide which is neutrally charged (or uncharged) such as peptide nucleic acid (PNA) for the formation of a duplex with its complementary target nucleic acid, wherein the formed duplex is separated via capillary gel electrophoresis (CGE), (column 8, lines 35-67; column 9, line 17; column 14, lines 40-67) rendering instant claim 1 anticipated.

Cummins et al. disclose that the oligonucleotide to which the duplex is formed with the target nucleic acid is, "of substantially the same length...N-3, N-2, and N-1 shortmers as compared to full length oligonucleotides" (column 11, lines 30-42; column 13, lines 24-28; column 14, lines 65-67), wherein the oligonucleotide is labeled (column 14, lines 54-56, thereby anticipating instant claims 2-11, 16, 17, 19, 20, and 23-27.

Therefore, Cummins et al. anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummins et al. (U.S. Patent No. 5,874,213, issued February 23, 1999) in view of Valdivia et al. (WO 96/36734, November 21, 1996).

Teachings of Cummins et al. have been discussed above.

Cummins et al. do not employ morpholino oligomers in their method (claims 21 and 22).

Valdivia et al. disclose the well-known advantage of higher binding affinity and improved hybridization (i.e., signal to noise) offered by morpholino oligomers as well as PNAs (page 11, lines 29-33; meeting instant claims 21 and 22).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made substitute the oligomer employed by Cummins et al. with

the morpholino oligomer of Valdivia et al. to arrive at the claimed invention for the following reasons.

The method of Cummins et al. employ a duplex formed between a PNA oligomer and its target nucleic acid for the purification and detection of the target nucleic acid. The method of Cummins et al. takes advantage of higher melting temperature of PNA oligomers in order to distinguish the duplexes formed between the naturally occurring DNAs and those formed between PNA oligomers and the target DNAs (column 13, lines 6-17).

MPEP, at 2143.02, states that the prior art can be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success. Since the advantage offered by PNA oligomers would have also been offered by morpholino oligomers (as evidenced by Valdivia et al.), one of ordinary skill in the art would have had a clear reasonable expectation of success in making the substitution of equivalent to arrive at the claimed invention with a reasonable expectation of success.

Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummins et al. (U.S. Patent No. 5,874,213, issued February 23, 1999) in view of Ness et al. (U.S. Patent No. 6,613,508 B1, issued September 2, 2003, filed July 22, 1997).

Teachings of Cummins et al. have been discussed above.

Cummins et al. do not employ an ion exchange medium for the separation of the duplexes.

Ness et al. disclose a wide-range of well-known size separation methods among which is ion-exchange HPLC method (column 4, lines 10-25).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the separation technique of Cummins et al. with a well-known size separation technique of ion-exchange HPLC to arrive at the claimed invention for the following reasons.

Cummins et al. disclose method of separating a duplex formed between nucleic acid and PNA. While the separation of the duplexes was performed by capillary electrophoresis, as evidenced by Ness et al., one of ordinary skill in the art would have readily recognized that any of the well-known size separation techniques would have been readily implemented with a reasonable expectation of success. Such is even acknowledged by the Applicants, wherein the instant specification discloses, "[a]ny charge-based separation technique useful for separating charged biopolymers may be used to separate the chared:uncharged duplexes formed by mixing the substantially uncharged analyte molecules with the charged nucleic acid or analog," (page 13, lines 22-25).

Since Ness et al. clearly disclose that separation of duplexes can be achieved via many well-known separation techniques, ranging from capillary electrophoresis to ion-exchange HPLC (column 4, lines 10-25; column 40, lines 64-65), one of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success in substituting the separation method of Cummins et al. with that of Ness et al. to arrive at the invention as claimed.

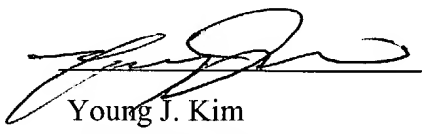
Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Young J. Kim
Patent Examiner
Art Unit 1637
6/16/04

yjk